



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,793	07/08/2005	Alexander Domling	62661(52171)	9957

21874 7590 07/17/2009  
EDWARDS ANGELL PALMER & DODGE LLP  
P.O. BOX 55874  
BOSTON, MA 02205

EXAMINER
----------

CHANG, CELIA C

ART UNIT	PAPER NUMBER
----------	--------------

1625

MAIL DATE	DELIVERY MODE
-----------	---------------

07/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/520,793	<b>Applicant(s)</b> DOMLING ET AL.	
	<b>Examiner</b> Celia Chang	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 11 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-23, 25-28 and 30-38 is/are pending in the application.
- 4a) Of the above claim(s) 35-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-23, 25-28, 30-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Amendment and response filed by applicants dated May 11, 2009 have been entered and considered carefully.

Claims 1-18, 24, 29 have been canceled. Claims 19-23, 25-28, 30-34 are pending. Claims 35-38 stayed withdrawn.

2. The rejection of claims 19-33 under 35 USC 102(b) over Gerhard '089 is dropped in view of the amendment limiting R<sup>8</sup> to H or alkyl.

3. The rejection of claims 19-34 under 35 USC 103(a) over Gerhard '089 in view of DE 19,638,870 is dropped in view of the amendment limiting R<sup>8</sup> to H or alkyl thus differ from the prior art in additional structure then mere leucine/isoleucine moieties.

4. The amendment and the affidavit filed under 37 CFR 1.132 necessitated the following new grounds of rejection.

Claims 19-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds wherein n=4, piperidinyl compounds, does not reasonably provide enablement for the compounds as now claimed wherein n=2, 3, or 5, i.e. 4, 5 or 7 membered ring compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Starting material and how to make the non-piperidinyl compounds such as formula IV nonpiperidinyl, are not seen but required. Absent of starting material, the public is offered mere language rather than enablement. In re Howarth 210 USPQ 689. Ex parte Moersch 104 USPQ 122.

In addition, cancer treatment is structural sensitive and cancer specific, that is, specific compounds can treat specific cancer. The national cancer institute has provided guidelines that for compounds to have broad "antiproliferation" activity, one compound from each category of the cancer panel should be active (see p.628). In the instant case, only n=4, piperidinyl

Art Unit: 1625

compounds have been shown to have inhibitory activity against carcinoma (see ACTT description). Nowhere in the specification that such breadth of compounds from 4 to 7 membered ring would have efficacy in treating or susceptible to all tumor, immune, autoimmune, inflammatory disease or rheumatoid arthritis. Each tumor, immune, autoimmune or inflammatory disease has a different etiology and/or symptom. Current medical treatment is for etiology and/or symptoms specifically. Nowhere in the prior art a single compound has been able to treat all tumor benign or malignant, all immuno/auimmuno disorder, or all inflammatory disorder from IBS to asthma. There is no antecedent basis of which cancer, what immuno/ auto-immuno disorder would the compounds be effective on. Nor was there any guidelines as to dosage, route of administration and duration for treating such condition. Further, nowhere in the specification provided enablement that who are the "susceptible" subject, whom without being diagnosed with any disease would be "prevented" from acquiring disease. Such a utility for a single compound is incredible.

It has been clearly delineated in the restriction requirement that to be rejoined with the product claims, method of use claims must be free from all other issues such as 112 first and second paragraph. In the instant case none of the claims 35-38 can be rejoined in view of the incredible scope of the claims as compared to the deficiency of descriptive as well as enablement support of the specification.

**5. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1625

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*July 14, 2009*

*/Celia Chang/*  
*Primary Examiner*  
*Art Unit 1625*